OCT 2 4 2001

K013191

510(k) Summary of Safety and Effectiveness

(1)	**Submitter's name:**	Encore Orthopedics, Inc.
	Submitter's address:	9800 Metric Blvd, Austin, TX 78758
	Submitter's telephone number:	(512) 834-6255
	Contact person:	Joanna Droege
	Date summary prepared:	September 21, 2001
(2)	**Trade or proprietary device name:**	PASS Spinal System
	Common or usual name:	Pedicle screw spinal system
	Classification name:	Class II
(3)	**Legally marketed predicate device:**	PASS Spinal System (K001024)

(4) **Subject device description:**

The subjects of this **Special 510(k)** submission are the addition of rod-plate components for the PASS Spinal System (K001024). All components are manufactured from titanium alloy (Ti-6Al-4V) that conforms to ASTM F136.

The rod-plates are similar to the rods as they consist of a short rod segment that has enlarged portions at the ends with holes to attach directly to the screws with hemispherical nuts rather than connecting the rod to the screw via a clamp. The proximal end is circular is shape with a circular hole, while the distal end is oval in shape with an oval opening that allows vertical variability of the distal screw placement. These components are offered in two versions (two or three holes) for one or two level instrumentation, each being available in two sizes, small and large. Rod-plates are present to match the lumbar lordosis.

(5) **Subject device intended use:**

The PASS Spinal System consists of pedicle screws, rods, nuts and crosslink members utilized to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

As a pedicle screw system, the PASS Spinal System is intended for the treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebrae in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

(6) **Performance data:**

The Food and Drug Administration have established no performance standards applicable to pedicle screw spinal systems. However, static and fatigue compression testing of the PASS Spinal System was performed according to ASTM F1717-96.

(7) **Basis for substantial equivalence:**

The Additional Components of the PASS Spinal System are equivalent to the other spinal systems commercially available that incorporate pedicle screws, rods, and crosslinking members, including the TTL Isobar Spinal System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 4 2001

Ms. Joanna Droege
Regulatory/QA Engineer
Encore Orthopedics, Inc.
9800 Metric Blvd.
Austin, Texas 78758

Re: K013191
Trade Name: PASS Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle Screw Spinal System
Regulatory Class: Class II
Product Code: MNI, MNH
Dated: September 21, 2001
Received: September 24, 2001

Dear Ms. Droege:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K013191

510(k) Number (if known): K013191

Device Name: Additional Components to PASS Spinal System

Indications For Use:

Additional Components to PASS Spinal System

Indications For Use

The PASS Spinal System consists of pedicle screws, rods, nuts and crosslink members utilized to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Yes OR Over-The-Counter Use No
(per 21 CFR 801.109)
(Optional Format 1-2-96)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013191

5/5/19